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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/433,418	11/04/1999	JOEL B. EPSTEIN	244/023	2559

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/433,418

Applicant(s)

EPSTEIN, JOEL B.

Examiner

Mojdeh Bahar

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-19,21-28 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-19,21-28 and 30-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/25/02 has been entered.

### ***Claim Objections***

Claims 37-39 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note that independent claim 1 recites the close transitional phrase "consisting of", EXCLUDING ALL OTHER ACTIVE PHARMACEUTICA AGENTS. Yet claims 37-39 add a second pharmaceutical agent to the composition employed in the method of claim 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 21-28, 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression, “a method of preventing an autoimmune disease of the mouth” in claim 19, line 1, renders the claims indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent autoimmune disease of the mouth are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those situations wherein prevention of autoimmune disease of the mouth be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some prevention, probable prevention, total prevention in most cases...etc.) herein because the specification does not disclose the extent of prevention achieved. Examiner would favorably consider the term “prophylaxis” over “prevention”.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 8, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggleston.

Eggleston teaches a method of treating aphthous ulceration employing topical azathioprine. Eggleston teaches treating patients with azathioprine pellets, see pages 233-234 and abstract in particular.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10, 12-19, 21-28, 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggleston. Lozada, and Sharpe et al. (USPN 5,637,616) Eggleston teaches a method of treating aphthous ulceration employing topical azathioprine. Eggleston teaches treating patients with 0.5 mg azathioprine pellets, taking four pellets at regular intervals, see pages 233-234 and abstract in particular.

Lozada teaches a method of treating patients with chronic inflammatory mucocutaneous disease having oral ulcerations including lichen planus, pemphigus vulgaris and bullous pemphigoid comprising administering azathioprine (an immunosuppressive agent), and a steroidal antiinflammatory agent see page 257 first full paragraph, see also MATERIALS AND METHODS. Lozada teaches that Azathioprine is administered from 5 mg every other day to 100 mg/day, see pages 258 Drugs and Results. See also page 259, Col. 2, first full paragraph as well as page 258 Adverse effects.

Sharpe et al. (USPN 5,637,616) teaches a method for topical treatment of mucosal lesions and in particular bullous pemphigoid, lichen planus, and aphthous ulcers employing gel, ointment, cream, foam, lotion or a solution that is orally applied, swished and expectorated or swallowed, see in particular claims 5-13. Sharpe et al. (USPN 5,637,616) also teaches that topical corticosteroids are known to be employed in treating aphthous ulcers, see col. 4, lines 41-47. Sharpe et al. (USPN 5,637,616) also teaches that bullous pemphigoid is known to be treated

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with immunosuppressive agents in addition to steroids and pemphigus is known to be treated with corticosteroids, such as prednisone and prednisolone as well as immunosuppressive agents such as azathioprine, cyclophamide, methotrexate and cyclosporine, see col. 3, lines 23-30; see also col. 2, 62-col. 3, line 4. Sharpe et al. also teaches the employment of anti-inflammatory agents in its composition, see in particular col. 10 lines 51-56. Finally, Sharpe et al. teaches that these oral lesions are accompanied by pain, see col 1, lines 39-43, see also col. 5, lines 32-36.

Eggleston, Lozada and Sharpe et al. (USPN 5,637,616) taken together, do not particularly teach the incorporation of NSAIDS in their methods.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ azathioprine (an immunosuppressive agent), and corticosteroids in a topical formulation employed in a method of treating autoimmune diseases of the mouth. It would have also been obvious to employ NSAIDS in their method.

One of ordinary skill in the art would have been motivated to employ azathioprine (an immunosuppressive agent), and corticosteroids in a topical formulation employed in a method of treating autoimmune diseases of the mouth because both agents individually are known to be useful in treating autoimmune diseases of the mouth. Combining two agents which are known to be useful to in treating autoimmune disease of the mouth individually into a single composition useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. Further the oral lesions symptomatic of autoimmune diseases of the mouth are known to be painful. The skilled artisan would have been motivated to add NSAIDS to formulations known to be useful in treating autoimmune diseases of the mouth because pain is known to be associated

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with these oral lesions. Optimization of amounts is within the purview of the skilled artisan and is therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
May 31, 2002

  
RUSSELL TRAVERS  
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GROUP 1200